



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,627	12/27/2001	Michael E. Miller	047711-0282	9533
7590 03/14/2005 TED R. RITTMASER FOLEY & LARDNER 2029 CENTURY PARK EAST SUITE 3500 LOS ANGELES, CA 90067-3021			EXAMINER MENDEZ, MANUEL A	
			ART UNIT 3763	PAPER NUMBER
DATE MAILED: 03/14/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,627

Applicant(s)

MILLER ET AL.

Examiner

Manuel Mendez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 10-33 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-6,10,11 and 23-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Claims 1, 3-6, 10-11 and 23-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/18/2004. The examiner of record will prosecute claims 12-22.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

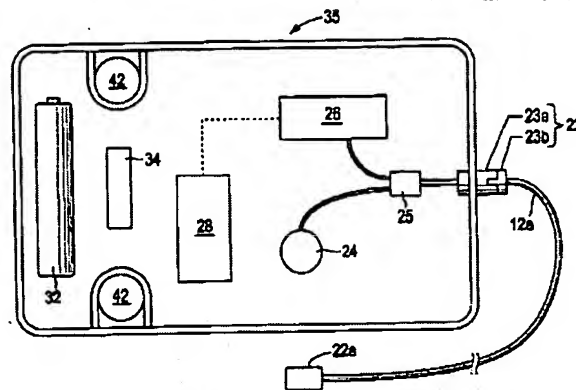
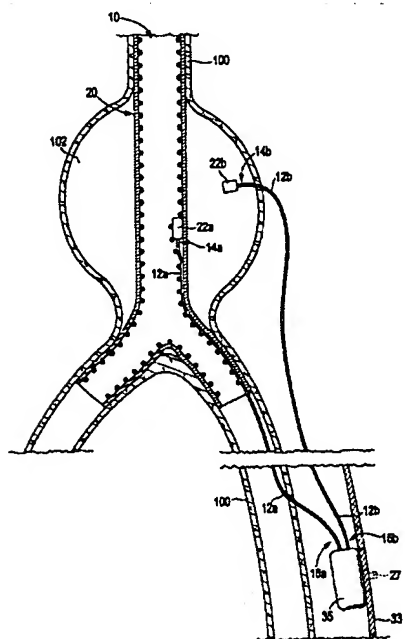
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by **DiCarlo**.



In figures 1 and 2, the DiCarlo patent shows an implant unit and a sensor for detecting a physiological parameter, the sensor being separate from and connectable to the implant unit, the implant unit is configured for implantation in a human body, the sensor is configured to be placed in an area of the human body, and the sensor being configured to be connected to the implant unit.

Claims 15-22 are apparatus claims. Accordingly, it is irrelevant to the patentability of the claims in question whether (1) this device is a non-vascular implant, and/or (2) whether the sensor is placed in an area of the body without passing the sensor through a vascular system. Importantly, limitations (1) and (2) are intended uses that do not provide any patentability weight to the claim. Moreover, since DiCarlo discloses all the structural elements cited in claim 15, it would be reasonable to conclude that DiCarlo anticipates claim 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **DiCarlo in view of Klein, et al., and Penner, et al.** The examiner considers that the steps of performing incisions to insert implants into the body and using sutures to attach sensors to body tissue are inherent to the teachings of DiCarlo. However, in order to expedite the prosecution of this case and avoid further argumentation, the examiner argues that the steps of doing incisions and using sutures are conventional in the art as evidenced by the teachings of Klein, et al.

In column 4, lines 58-65, the specification of Klein, et al., expressly discloses sutures holes (13) demonstrating the conventionality of using sutures to attach implanted medical devices to body tissue. Additionally, in column 5, lines 12-14, the specification teaches the benefits of performing minimum incision sizes, and further down in the same paragraph, the specification again mentions the use of sutures to attach an implanted medical device to body tissue.

Based on the above observations, for a person of ordinary skill in the art, modifying or enhancing the DiCarlo apparatus by using incisions to insert implanted medical devices into the body, and sutures as taught by Klein, et al., would have been considered obvious in view of the conventionality of these surgical procedures.

Finally, the examiner included in this rejection Penner, et al., to demonstrate that the challenges of attaching remote sensors to monitoring circuitry have been considered by other artisans in the art. Accordingly, Penner, et al., uses a wireless connection between the sensor and the monitoring circuitry to eliminate the challenges of connecting control circuitry with remote sensors. Based on the teachings of Penner, et al., modifying the DiCarlo apparatus with wireless capabilities that connects the sensors located in remote areas with monitoring systems would have been considered an obvious design choice.

Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over **DiCarlo in view of Klein, et al., and Penner, et al., and in further view of Ellinwood, Jr., Lewis, et al., and Blackshear, et al.**

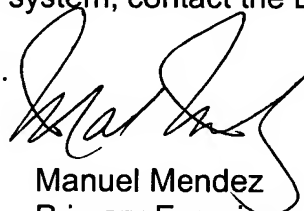
The Ellinwood, Jr., patent demonstrates the conventionality of using an implant as a pump, having electronics, delivering a drug to the human body and wherein the sensor comprises a sensing element. The Lewis, et al., patent demonstrates that the use of biomolecules as sensors is well known in the art; and finally, Blackshear, et al., demonstrates that implantable pumps can be used for the infusion of insulin.

According to the above observations, for a person of ordinary skill in the art, modifying the apparatus disclosed by DiCarlo with any of the above enhancements would have been considered obvious in view of the proven conventionality of these enhancements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez
Primary Examiner
Art Unit 3763

MM